

REMARKS

The application has been carefully reviewed in light of the Office action, and amended as necessary to more clearly and particularly describe the subject matter that Applicant regards as the invention.

In this Amendment "D", claims 1, 4-12 and 15 have been amended and new claims 19 and 20 have been added. Reconsideration of the application in its current format is hereby respectfully requested.

In the Office action, the Examiner has made the restriction requirement final and withdrawn claims 3,13,14 and 16-18. In the Office action, the Examiner asserts that the Applicant made the argument "that a common structure is present between the polypeptides of SEQ ID Nos. 1-9". Applicant would like to clarify that this was not the argument Applicant had made. The Applicant made the argument that there was common structure *within each* sequence. This argument was made in response to an oral requirement made by the prior Examiner.

The Examiner also states that "claims 11 and 12 have been characterized by applicants as 'method' claims". Applicant would like to clarify that Applicant did not characterize claims 11 and 12 as being method claims. It was the prior Examiner that characterized claims 11 and 12 as being method claims. Applicant was merely paraphrasing what the prior Examiner had stated in her Office action.

In the Office action, the Examiner has rejected claims 1, 2, 4-12 and 15 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. In making this rejection, the Examiner noted that the recitation of "sequences derived therefrom" in claim 1 was limitless and that "applicants are not in possession of all such sequences". The Examiner also stated that "The absence of proof of the existence of such prior binding substances means that applicants cannot have provided sufficient written description to indicate that they are in possession of the disclosed invention". This latter reasoning is tied into the §101 rejection made by the Examiner, which is discussed below. In response to the Examiner's rejection based on lack of a written description, Applicant has amended claim 1 to remove the recitation of "sequences derived therefrom". Applicant has also amended claim 1 to include the limitations of claim 2, which has been canceled.

The Examiner has also rejected claims 1, 2, 4-12 and 15 under 35 U.S.C. §101 because it is the Examiner's position that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. In conjunction with this rejection, the Examiner has also rejected claims 1, 2, 4-12 and 15 under 35 U.S.C. §112, first paragraph, for lack of enablement. The reasoning provided by the Examiner for these rejections is that:

"Nobody knows what causes the conformational transformation that results in the disease state and both conformations have the same sequence. The way the antibody was generated did not take conformation into account when it was created from the mapping experiments and, thus, it is not clear to which conformer the antibody actually binds. Since the existence of a PrP^{Sc}-binding substance is crucial for the invention and since no such substance has been proven to exist the claims lack a specific and substantial utility."

Based on the foregoing statement and the statement made by the Examiner with regard to the lack of a written description requirement, it is clear that the Examiner's 35 U.S.C. §101 rejection and 35 U.S.C. §112, first paragraph rejection are based on a finding that the asserted specific and substantial utility *is not credible* and that this lack of credibility is due to the non-existence of PrP^{Sc}-binding substances. The Examiner, however, has not provided any evidence to support this finding. MPEP §2107 II(C)(2) provides that in order to establish a prima facie showing of no specific and substantial credible utility (based on a lack of credibility), the "prima facie showing must contain the following elements:

- (i.) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
- (ii.) Support for factual findings relied upon in reaching this conclusion; and
- (iii.) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art."

Since the Examiner has failed to provide any support for his factual finding that PrP^{Sc}-binding substances do not exist, Applicant submits that the Examiner has failed to establish a prima facie showing of no specific and substantial credible utility. Although the Examiner has failed to establish a prima facie showing of no specific and substantial credible utility, Applicant has submitted herewith a supplemental

information disclosure statement setting forth references showing that persons skilled in the art do indeed consider PrP^{Sc}-binding substances to be in existence. In fact, Applicant notes that U.S. Patent No. 6,537,548 to Prusiner et al., U.S. Patent No. 6,451,541 to Winnacker et al., U.S. Patent No. 6,290,954 to Prusiner et al. and U.S. Patent No. 6,372,214 to Prusiner et al. all contain claims reciting a PrP^{Sc}-binding substance. Since these patents were issued by the U.S. Patent Office, it is clear that the U.S. Patent Office also considers PrP^{Sc}-binding substances to be in existence. Accordingly, Applicant respectfully submits that claims 1, 2, 4-12 and 15 meet the requirements of 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph and notice to that effect is hereby respectfully requested.

The Examiner has rejected claims 1, 11, 12 and 15 under 35 U.S.C. §102(b) as being anticipated by naturally occurring prion protein. Applicant submits, however, that "isolated" polypeptides do not occur naturally and, thus, a "synthetic *isolated* polypeptide" (emphasis added), as presently recited in claims 1, 11, 12 and 15 is not anticipated by naturally occurring prion protein.

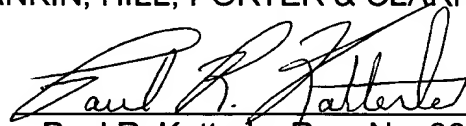
In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. SCH-32409.

Respectfully submitted,

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By


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